COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 20-X-2006
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NOT FOR PUBLICATION

COMMISSION DECISION

of 20-X-2006

amending the marketing authorisation for "Faslodex - Fulvestrant", a medicinal product for human use, granted by Decision C(2004)851

(ONLY THE ENGLISH TEXT IS AUTHENTIC)

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(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency[1],

Having regard to Commission Regulation (EC) No 1085/2003 of 3 June 2003 concerning the examination of variations to the terms of a marketing authorisation for medicinal products for human use and veterinary medicinal products falling within the scope of Council Regulation (EEC) No 2309/93[2], and in particular the first subparagraph of Article 6(10) thereof,

Having regard to the application(s) submitted by AstraZeneca UK Limited on 28 May 2006 under Article 6(1) of Commission Regulation (EC) No 1085/2003,

Having regard to Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use[3], and in particular Article 61(3) thereof,

Having regard to the opinion of the European Medicines Agency, formulated by the Committee for Medicinal Products for Human Use on 21 September 2006,

Whereas:

(1) An examination of the major variation(s) type II to the terms of the marketing authorisation for the medicinal product "Faslodex - Fulvestrant", which is entered in the Community Register of Medicinal Products under No(s) EU/1/03/269/001 and the placing on the market of which was authorised by Decision C(2004)851

[1] OJ L 136, 30.4.2004, p. 1
[2] OJ L 159, 27.6.2003, p. 24.
[3] OJ L 311, 28.11.2001, p. 67. Directive as last amended by Directive 2004/27/EC (OJ L 136, 30.4.2004, p. 34).

of 10 March 2004, has shown that the product remains in compliance with the requirements set out in Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use[4].

(2) It is therefore appropriate to accept the application(s) in respect of (a) major variation(s) to the terms of the marketing authorisation and to amend Decision C(2004)851 accordingly.

(3) AstraZeneca UK Limited submitted, under Article 61(3) of Directive 2001/83/EC, a notification(s) for changes to an aspect of the labelling or the package leaflet, which has (have) not yet been included in Decision C(2004)851 of 10 March 2004.

(4) The marketing authorisation should be updated, and Decision C(2004)851 amended accordingly.

(5) For the sake of clarity and transparency, it is advisable, following the amendment of part or parts of the Annexes, to provide for a consolidated version thereof. The Annexes to Decision C (2004)851 should therefore be replaced,

HAS ADOPTED THIS DECISION:

Article 1

Decision C(2004)851 is amended as follows:

1) The following list of notifications for changes to an aspect of the labelling or the package leaflet is added to the updated marketing authorisation;

Application number	Annex (EU numbers affected)
EMEA/H/C/540/N/004	IIIAB (EU/1/03/269/001)

2) Annex I is replaced by the text set out in Annex I to this Decision;

3) Annex III is replaced by the text set out in Annex III to this Decision.

[4] OJ L 311, 28.11.2001, p. 67. Directive as last amended by Directive 2004/27/EC (OJ L 136, 30.4.2004, p.34).

Article 2

This Decision is addressed to AstraZeneca UK Limited, Alderley Park, Macclesfield, Cheshire, SK10 4TG United Kingdom.

Done at Brussels, 20-X-2006

For the Commission
Heinz ZOUREK
Director-General